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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,907	12/30/2003	Saskia Marc Antoinette Van De Zande	2002.028 US C1	1430

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EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/749,907	Applicant(s) ANTOINETTE VAN DE ZANDE ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on August 10, 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,9-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,9-11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's response filed August 10, 2005 is acknowledged and entered. Claims 1, 4-6, 9-11 and 13-16 are pending and under examination. The declaration of William P. Ramey regarding the deposited material (ECACC accessions 99011472, 99011473 and 99011474) is acknowledged and has been considered. The declaration satisfies the biological deposit requirements for the above named antibodies.
2. The following objection and rejections are either moot or withdrawn:
  - The objection to claim 7 for reciting the acronym, "IFT" and not providing a complete spelling at its first recitation is moot in view of the cancellation of claim 7.
  - The rejection of claims 2, 7 and 8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is moot in view of the cancellation of those claims 2, 7 and 8.
  - The rejection claims 1-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is moot in view of cancelled claims 2, 3, 7, 8 and 12.
  - The rejection of claim 1, 8-10, 12, 13 and 16 under 35 U.S.C. 102(b) as being anticipated by Rekik *et al.* (*Avian Diseases*, 1992, 36:237-246) is moot with regard to claims 8 and 12, now cancelled, and withdrawn with regard to claims 1, 9, 10, 13 and 16 in view of Applicant's amendment. *Please note that this rejection is withdrawn solely because of the limitations (improper new matter) added to claim 1 and all dependent claims in the amendment of August 10, 2005. Should Applicant remove the new matter, this rejection may be reinstated.*

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- The rejection of claims 1, 3-6, 8-10, 12-16 under 35 U.S.C. 103(a) as being unpatentable over Rekik *et al.* in view of Ashmead *et al.* (US 5,162,369) and Rosenberger *et al.* (US 5,525,342) is moot with respect to claims 3, 8 and 12, now cancelled, and withdrawn with respect to claims 1, 4-6, 9, 10 and 13-16 in view of Applicant's amendment. *Please note that this rejection is withdrawn solely because of the limitations (improper new matter) added to claim 1 and all dependent claims in the amendment of August 10, 2005. Should Applicant remove the new matter, this rejection may be reinstated.*

#### ***Claim Objections***

3. (New objection) Claims 1, 4-6, 9-11 and 13-16 are objected for the following informality: Claim 1 and dependent claims recite a misspelling of the term, "ECACC".

#### ***Claim Rejections - 35 USC § 112***

4. (New rejection) Claims 1, 4-6, 9-11 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim limitations added to claim 1 and all depending claims constitutes new matter that was not present in the application at the time of filing.

The claims as amended recite, "A method of propagating an avian Reovirus, belonging to an antigenic class of avian Reovirus ERS isolates, on Vero cells, without prior adaptation,

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wherein the avian Reovirus is able to induce antiserum in an animal, which antiserum causes a reduction of the plaques formed by avian Reovirus ERS, **a sample which is deposited at the ECACC under accession no. 99011475, of at least 75%** in a plaque reduction assay and wherein the avian Reovirus positively reacts with polyclonal avian Reovirus antiserum but not with monoclonal antibodies identified by accessions nos. 99011472, 99011473 and 99011474, samples of which are deposited at the ECAC” [underline and bold emphasis added], *etc.* This deposited material and 75% plaque reduction is not described in the specification. Therefore, Applicant was not in possession of the claimed invention at the time of filing the instant application.

It is noted that Applicant refers to USSN 09/493,484, now US Patent 6,951,650, issued on October 4, 2005. This application is in no way related to the referenced patent. The attempt to incorporate subject matter into this application by reference to US 6,951,650 is ineffective because incorporations by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f). See MPEP 2163.07(b) and 608.01(p) for Office policy regarding incorporation by reference. If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

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5. (*New rejection*) Claims 1, 4-6, 9-11 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the Reovirus strain deposited at the ECACC under accession number 99011475 is required to practice the claimed invention because it is a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. The specification does not disclose any information about strain 99011475.

When a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808. In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

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6. Claims 1, 4-6, 9-11 and 13-16 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of propagating ERS 1037, ERS 060E and ERS 074 in Vero cells without prior adaptation, does not reasonably provide enablement for a method of propagating any avian Reovirus without prior adaptation to Vero cells.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that the claims as amended recite a specific class of avian Reovirus, thus limiting the scope of the invention to a smaller class of avian Reovirus. In response to Applicant's argument, the amendment to the claims does not limit the scope of the avian Reovirus to any particular ERS isolate. Claim 1 recites as an example, ERS isolate 99011475, however the wording of the claim does not limit the claim to a particular isolate. The scope of the claims includes any ERS isolate, which is not enabled for reasons of record set forth in the previous Office action.

7. Claims 1, 4-6, 9-11 and 13-16 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of propagating avian Reovirus that are isolated from poultry and grown to suitable titer on Vero cells, without prior adaptation, comprising the steps of inoculating a Vero cell line with the avian Reovirus, allowing the Reovirus to multiply, and harvesting the avian Reovirus. The claims encompass embodiments

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that are not adequately described, namely, avian reoves isolated from the wild, that do not require adaptation to a Vero cell line and produce particular titers.

Applicant's arguments have been carefully considered but fail to persuade. Applicant argues that the claims as amended recite a specific class of avian Reovirus, thus limiting the scope of the invention to a smaller class of avian Reovirus. In response to Applicant's argument, the amendment to the claims does not limit the scope of the avian Reovirus to any particular ERS isolate. Claim 1 recites as an example, ERS isolate 99011475, however the wording of the claim does not limit the claim to a particular isolate. The scope of the claims includes any ERS isolate, for which Applicant has not demonstrated possession for the reasons set forth in the previous Office action.

8. Claims 1, 4-6, 9-11 and 13-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a method of propagating an avian Reovirus belonging to an antigenic class of avian Reovirus ERS isolates. Regarding claims 1, 4-6, 9-11 and 13-16, the phrase "a sample of which" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Specifically, it is not clear whether the ECACC no. 99011475 is meant to be included in the claimed invention since it is just a sample of an ERS isolate.

### ***Conclusion***

9. No claim is allowed.



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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
October 31, 2005